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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,050	12/20/2001	Nikolaos V. Tsekos	600.466US2	4434
21186	7590	09/17/2004	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			SHAW, SHAWNA JEANNINE	
			ART UNIT	PAPER NUMBER
			3737	

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/028,050	Applicant(s) TSEKOS	
	Examiner Shawna J. Shaw	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 26-56 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

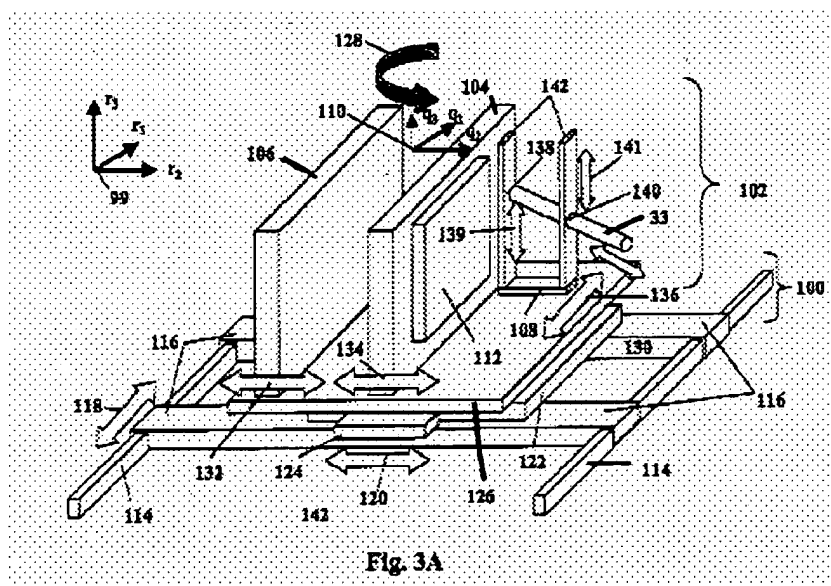
Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Response to Arguments***

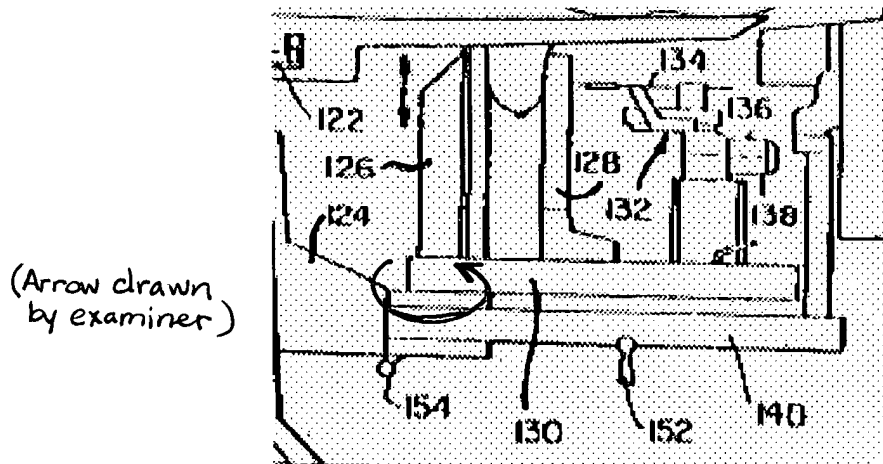
1. Applicant's arguments filed 06/18/2004 have been fully considered but they are not persuasive. Regarding claims 27-43, 48 and 51-56, the examiner maintains that Siczek et al. disclose a stage/platform (130) coupled a probe guide (132) and first and second compression surfaces (128, 126) and adapted to rotate on a second axis substantially orthogonal to the first axis (col. 11 lines 46-49), as recited in claims 27 and 51. Since applicant is not able to discern the recited element(s) in the figures and detailed description of Siczek, the examiner will refer to figures 7 and 12A of the cited patent as compared with figure 3A of the applicant's present invention:

Figure 3A of the present application demonstrates a stage (126), coupled to probe guide (33) and first and second compression surfaces (104, 106) and adapted to rotate on a second axis substantially orthogonal to the first axis (as depicted by arrow 128):

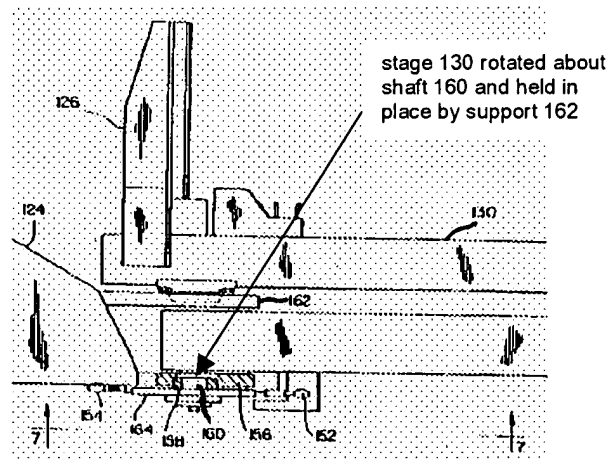


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Figure 7 of Siczek also shows a typical stage (130) coupled to a probe guide (132) and first and second compression surfaces (128, 126) and "arranged to pivot radially in a horizontal plane about its connection point to arm carrier 124" (col. 11 lines 46-49):



This can be further demonstrated in Figure 12A of Siczek where it is shown that the stage (130) is rotated about shaft 160:



With respect to the term "stage," for examination purposes, the examiner has used the ordinary custom meaning which according to Merriam-Webster's Online Dictionary is defined as: "2 a (1) : a raised platform."

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Regarding claims 44-50, in response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Regarding the combined stereotactic breast biopsy teachings of Siczek and Russell, one of ordinary skill in the art would readily appreciate that an open window as demonstrated by Russell would provide less restricted access to the compressed breast in terms of a wide range of possible advancement angles (as desired by Siczek as demonstrated by vertical and horizontal stages for angularly positioning the biopsy probe) previously limited by fenestrated compression plates which typically only allow advancement in one direction. In addition, a window as demonstrated by Russell obviates direct contact of the compression plate with the region of interest and with the probe carrying the tissue sample, thereby reducing possible contamination of the patient and compression plate. Regarding the combined stereotactic probe placement teachings of Siczek, Russell and Chakeres, Chakeres provides motivation for the use of a thin permeable cover having markings thereon so as to accurately guide a probe to an entry point with a high level of precision (col. 1 lines 15-20, col. 3 lines 25-45). Moreover, one of ordinary skill in the art would appreciate that the thin disposable cover would in

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no way constrain the point of entry of the probe and can be readily discarded so as to avoid contamination of the next procedure. Regarding the combined mammographic teachings of Siczek and Panetta, one of ordinary skill in the art would readily appreciate that plastic or polycarbonate compression plates are extremely well known in the art for their suitability for breast examination and affordability as evidenced e.g., by Panetta of record (col. 2 lines 40-43), Virta (col. 6 lines 9-15) and Evans (col. 2 lines 47-55).

Applicant's arguments have overcome the rejection of claims 49 and 50 under 35 USC 112 second paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 27-43, 48 and 51-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Siczek et al.

Regarding claims 27-37, 40-43, 48, 51-54 and 56, Siczek et al. teaches a mammographic biopsy apparatus including first and second compression plates (128, 126), compression adjuster (col. 12 line 67 – col. 13 line 4), stage/platform (130), and probe guide (132). Siczek et al. further discloses wherein: the linear

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movement of the compression plates; the vertical and rotational position of stage (130) with respect to supporting surface (120); and the angle and depth of the probe guide (132), are controlled via conventional motorized mechanisms in a remote fashion using a control handle or footswitch. See col. 11 lines 31-49 and col. 12 line 62 – col. 13 line 19. Regarding claims 38 and 39, Siczek et al. discloses wherein support surface (120) is adapted to rotate along an axis parallel to the spine of a patient (see fig. 8 and col. 13 lines 36-47). Further regarding claim 55, it appears from figure 7 that the probe (134) is passed through compression plate (128).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Siczek et al. in view of Russell et al.

Regarding claim 44, Siczek et al. differs from the claimed invention in that a window is not specifically addressed. Russell et al. teaches performing a breast biopsy through a compression plate having a window (26). It would have been obvious at the time the invention was made to a person of ordinary skill in the art to use a first compression plate having a window as taught by Russell et al. in the invention as taught by Siczek et al. to provide less restricted access to the target region and to avoid contamination of the compression plate.

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4. Claims 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siczek et al. in view of Russell et al. and further in view of Chakeres.

Regarding claims 45-47, Siczek et al. and Russell et al. differ from the claimed invention in that a permeable or mylar cover is not specifically addressed. Chakeres teaches advancing a probe through an imager compatible covering (composed of e.g., mylar) having markings thereon. See col. 15 lines 45-48 and col. 16 lines 42-49. It would have been obvious at the time the invention was made to cover the window of Siczek et al. in view of Russell et al. with a stereotactic covering as taught by Chakeres to provide more accurate needle guidance while maintaining a sterile procedure.

5. Claims 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siczek et al. in view of Panetta et al.

Regarding claims 49 and 50, Siczek et al. differs from the claimed invention in that the composition of the components is not addressed explicitly. Panetta et al. discloses a mammographic system having plastic components (see elements 30, 45 and 65). It would have been obvious at the time the invention was made to a person of ordinary skill in the art to use plastic materials in the biopsy system of Siczek et al. as taught by Panetta et al. as a cheaper, well known expedient in the art.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is

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filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


7. This application contains claims 1-13 and 26 drawn to an invention nonelected without traverse in Paper No. 03152004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawna J. Shaw whose telephone number is (703) 308-2985. The examiner can normally be reached on 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Shawna J. Shaw', with a stylized, cursive script.

Shawna J. Shaw
Primary Examiner
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09/14/2004